IN THE UNITED STATES PATENTS AND TRADEMARK OFFICE

Applicant:	Penford Australia Limited
Serial No:	10/009,023
Filed:	April 6, 2001
Title:	Starch sub-types and lipid metabolism
Inventors:	BROWN *et al*

DECLARATION UNDER 37 CFR 1.132

I, Ian L. Brown, of 24 Hancock Court, Basking Ridge, 07920, New Jersey, United States of America, a citizen of the Commonwealth of Australia, declare that:-

1. I am one of the inventors of the subject matter of US Patent Application Serial No. 10/009,023 (the present application) filed on April 6, 2001.

2. My qualifications and technical experience are set out in my curriculum vitae, a copy of which is attached as Annexure A.

3. The present application relates to a method for regulating carbohydrate and fat metabolism in an individual (the present invention). The basis of the present invention is the unexpected finding that replacing a proportion of the individual's daily carbohydrate intake with resistant starch and a proportion of the individual's saturated fat intake with unsaturated fat has beneficial metabolic effects.

4. The desired metabolic effects of the present invention include reduced post-prandial plasma concentrations after meal intake, as well as lower plasma insulin levels, a reduction in plasma leptin concentrate together with an increase in satiety; and a decrease in the levels of lipid deposition in white adipose tissue, brown adipose tissue and muscle tissue together with an increase in glycogen synthesis in the liver (see page 14 lines 1-6).

5. To examine in detail the metabolic effects of diet on the regulation of carbohydrate and fat metabolism, we investigated the effect of four diets on plasma glucose, plasma insulin, plasma leptin and C-fos brain activity following a 16 week dietary protocol (see Figures 4, 5

and 6). The four diets comprised 1) saturated fat/amylopectin, 2) saturated fat/amylose, 3)unsaturated fat (N-3)/ amylopectin and 4) unsaturated fat(N-3)/ amylose.

6. Results showed that for plasma glucose concentrations, in response to a 2-hour intravenous glucose challenge, the saturated fat/amylopectin diet is significantly different from the unsaturated fat (N-3)/ amylopectin diet, while the unsaturated fat(N-3)/ amylose diet is significantly different from the unsaturated fat (N-3)/ amylopectin (see Figure 4). With regard to fasting leptin concentrations there were significant differences between the starch groups (see Figure 5). Specifically, it was shown that consumption of a diet high in resistant starch and unsaturated fats or lipids leads to reduced post-prandial plasma glucose concentrations after meal-intake, as well as lower plasma insulin levels and a reduction in plasma leptin concentrations.

7. With regard to C-fos brain activity, results showed that transcription of c-fos is modulated significantly in the dorsomedial hypothalamic nucleus (DMH), arcuate hypothalamic nucleus (ARC), lateral hypothalamus (LH), paraventricular hypothalamic nucleus (PVN) and ventromedial hypothalamic nucleus (VMH) in response to diet. C-fos transcription is an indicator of neuronal activity. Accordingly, the observations made are important since these regions of the brain are known to play a role in regulation of energy balance and satiety.

8. The data from neuronal (c-fos) activity presents evidence that diets high in unsaturated fats and resistant starch have decreased activation of the hunger centre (LHA) whereas diets high in saturated fat and low in resistant starch had the opposite effect. The result is consistent with the change in satiety and plasma leptin concentrations.

9. The unexpected finding that consumption of a diet high in resistant starch and unsaturated fats results has desirable effects on plasma glucose, plasma insulin, plasma leptin and C-fos brain activity provides valuable information for the regulation of carbohydrate and fat metabolism in an individual. The surprising results of the invention are beneficial as it is known in the art that carbohydrate and fat metabolism plays a crucial role in the

development of insulin resistance, which is in turn understood to be the underlying cause of a range of metabolic diseases.

DECLARED at Bridgewater this 13 day of October, 2003

Ian L Brown

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This is Annexure A referred to in the Statutory Declaration of Ian L. Brown made before me this 13th day of October, 2003

DECLARED at Bridgewater, NJ this 13th day of October, 2003

Janet S. Chubrick

~~Ian L Brown~~

JANET S. CHUBRICK
NOTARY PUBLIC OF NEW JERSEY
My Commission Expires November 17, 2006